IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, Plaintiff, v. PHARM D SOLUTIONS, LLC a corporation, and LUIS R. DE LEON and JUAN C. DE LEON, individuals, Defendants.	)	Civil Action No. 4:19-cv-1813 **COMPLAINT FOR PERMANENT INJUNCTION**

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and this court's inherent equitable authority, to permanently enjoin the defendants, Pharm D Solutions, LLC ("Pharm D"), a corporation, and Luis R. De Leon and Juan C. De Leon, individuals (collectively, "Defendants"), from: (a) violating 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A), 351(a)(2)(B), and 351(c), and a certain drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1); (b) violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), and to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce; and (c) violating 21 U.S.C. § 331(d) by introducing and causing to be introduced, and

delivering and causing to be delivered for introduction, into interstate commerce, a new drug, as defined by 21 U.S.C. § 321(p), that is neither approved under 21 U.S.C. § 355, nor exempt from approval.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants and Their Operations

4. Pharm D is a Texas corporation currently located at 1304 South Loop West, Houston, Texas, within the jurisdiction of this Court. Pharm D has been manufacturing drug products since April 2015 and holds an active pharmacy license in the state of Texas. Pharm D first registered as an outsourcing facility pursuant to 21 U.S.C. § 353b on August 6, 2014, and maintained annual registrations through its most recent registration on October 25, 2017, which expired on December 31, 2018. As of the date of this filing, Pharm D has not re-registered as an outsourcing facility.

5. Dr. Luis De Leon is Pharm D's Pharmacist-in-Charge and fifty percent owner. Defendant Luis De Leon is the person most responsible for Pharm D's operations, including, but not limited to, manufacturing, licensing, complying with state and federal regulations, quality operations, labeling, and handling complaints and conducting recalls. Defendant Luis De Leon performs his duties at Pharm D, within the jurisdiction of this Court.

6. Juan C. De Leon is a pharmacist at Pharm D and fifty percent owner. Defendant Juan De Leon also participates in manufacturing, including supervising technicians and signing

off on production records and labeling, and handling sales and marketing. Defendant Juan De Leon performs his duties at Pharm D, within the jurisdiction of this Court.

7. During their regular course of business, Defendants manufacture, process, pack, label, hold, and distribute articles of drug, within the meaning of 21 U.S.C. § 321(g)(1), including sterile injectable drugs and sterile lyophilized drug products. Sterile drugs include drugs that are required to be sterile under Federal or state law or drugs that, by nature of their intended use or method of administration, are expected to be sterile ("sterile drugs"). *See* 21 U.S.C. § 353b(d)(5). Defendants' sterile injectable drug products include, among others, testosterone cypionate, glutathione, sterile water for injection, and magnesium chloride. Defendants' sterile lyophilized drug products include human chorionic gonadotropin (HCG) and Trimix (papaverine/phentolamine/alprostadil). During their regular course of business, Defendants distributed their drug Testosterone Cypionate/Propionate 200 mg/10 mg/1 mL Injectable with labels that omitted the required statement "This is a compounded drug."

8. Prior to December 31, 2018, Defendants filled orders for compounded drugs for "office use" (also referred to as "office stock") to doctors' offices throughout the United States. Defendants also fill orders directly to patients pursuant to patient-specific prescriptions which are distributed within the state of Texas.

9. Defendants manufacture drugs at Pharm D using components that were shipped in interstate commerce, including components from Minnesota.

The Act's Requirements

10. Under the Act, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), and that is "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C).

11. A drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

12. The Act requires that drugs be manufactured in accordance with current good manufacturing practice ("CGMP"). 21 U.S.C. § 351(a)(2)(B); *see also* 21 C.F.R. § 210.1(b). A drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP to assure that it meets the requirements of the Act as to safety and that it has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, regardless of whether the drug is actually defective in some way. FDA has promulgated CGMP regulations for drugs at 21 C.F.R. Parts 210 and 211.

13. A drug is deemed to be adulterated if it is not subject to the provisions of 21 U.S.C. § 351(b), and "its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess." 21 U.S.C. § 351(c).

14. A drug is deemed to be misbranded "unless its labeling bears adequate directions for use." 21 U.S.C. § 352(f)(1).

15. The Act requires, subject to certain exceptions not applicable here, that drug manufacturers obtain FDA approval of a new drug application ("NDA"), an abbreviated new drug application ("ANDA"), or an investigational new drug application ("IND") with respect to any new drug they introduce into interstate commerce, 21 U.S.C. §§ 331(d), 355(a). A "new drug" includes any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety

and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

16. The label of a drug compounded in an outsourcing facility must contain several specified statements and information, including the statement "This is a compounded drug" (21 U.S.C. § 353b(a)(10)(A)(i)), to be eligible for the exemptions applicable to outsourcing facilities.

The Act's Exemptions for Compounded Drugs

17. Compounding generally refers to the practice in which a licensed pharmacist or physician (or, in the case of an "outsourcing facility," a person under the direct supervision of a licensed pharmacist) combines, mixes, or alters ingredients to create a drug. Under the Act, "compounding" by outsourcing facilities "includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug." 21 U.S.C. § 353b(d)(1). Compounded drugs generally are tailored to the needs of identified individual patients, although outsourcing facilities are not required to obtain prescriptions for identified individual patients. *See* 21 U.S.C. § 353b(d)(4)(C).

18. Under the Act, an "outsourcing facility" is a facility that engages in the compounding of sterile drugs, registers as an outsourcing facility pursuant to 21 U.S.C. § 353b(b) and complies with all of the requirements of 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(d)(4)(A).

19. Under the Act, drug products compounded in a registered outsourcing facility are exempt from adequate directions for use and premarket approval requirements if the drugs compounded by the outsourcing facility are compounded in accordance with all of the conditions in 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(a).

20. Outsourcing facilities under 21 U.S.C. § 353b are not exempt from complying with CGMP. *See* 21 U.S.C. § 353b(a).

FDA's August 2018 Inspection

21. FDA conducted its most recent inspection of Pharm D between August 13 and 28, 2018 ("2018 Inspection").

22. FDA investigators observed and documented numerous insanitary conditions, as described further in paragraph 27 below, and violations of CGMP, as described further in paragraph 33 below.

23. As discussed further in paragraph 34 below, FDA investigators also observed and documented that Defendants manufactured and introduced into interstate commerce two lots of a drug that had strengths that differed from that which they purported or were represented to possess.

24. As discussed further in paragraphs 38 and 43 below, FDA also observed and documented that Defendants manufactured and introduced into interstate commerce a drug with labels that omitted information required by 21 U.S.C. § 353b(a)(10)(A).

25. At the close of the 2018 Inspection, FDA investigators issued a Form FDA-483, List of Inspectional Observations ("FDA-483") to Defendant Luis De Leon and discussed the FDA-483 observations with him.

26. On September 10, 2018, Pharm D announced a voluntary nationwide recall of all lots of unexpired sterile compounded drugs and temporarily ceased sterile drug operations. Pharm D resumed sterile compounding on October 8, 2018, and began limited distribution of three drugs intended to be sterile on October 24, 2018. Pharm D voluntarily ceased sterile drug operations again on November 9, 2018. Pharm D has since resumed sterile drug operations.

Adulteration Due to Insanitary Conditions

27. The insanitary conditions observed by FDA at the Pharm D facility during FDA's 2018 Inspection establish that drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). The insanitary conditions observed by FDA during the 2018 Inspection include, but are not limited to:

a. Failure to use appropriate aseptic technique while producing drug products intended to be sterile by, for example, blocking unidirectional high efficiency particulate air (HEPA) flow while compounding, employees leaning into sterile areas with exposed bare skin, failing to properly disinfect items before placing them in sterile areas, failing to take appropriate measures to prevent contamination prior to entering sterile areas, and failing to maintain clean air supply while handling products intended to be sterile and exposing these products to non-clean air;

b. Failure to ensure that the flow of air and components in sterile compounding areas is designed to prevent contamination;

c. Failure to verify that sterile compounding areas are suitable for sterile drug production by using adequate smoke studies;

d. Failure to adequately clean and disinfect rooms and equipment used to produce aseptic drug products by, for example, using non-sterile disinfectants and wipes, using sterile alcohol prep pads with no expiration date, and failing to establish appropriate contact times for sterile disinfectants;

e. Failure to implement adequate environmental monitoring systems by, for example, failing to utilize appropriate environmental monitoring media plates to support the

growth of microorganisms, and to conduct environmental monitoring excursion investigations for microbial contamination, mold, and yeast recovered from sterile processing areas; and

f. Failure to engage in appropriate gowning practices to prevent drug products from contamination by, for example, using bare hands during gowning and exposing bare skin after gowning.

28. Defendants violate 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.

29. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due to CGMP Violations

30. During the 2018 Inspection, FDA investigators documented numerous deviations from CGMP requirements for drugs, including but not limited to Defendants' failure to:

a. Establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, including validation of all aseptic and sterilization processes, designed to prevent microbial contamination of drug products purporting to be sterile, *see* 21 C.F.R. § 211.113(b);

b. Establish adequate control systems necessary to prevent contamination during aseptic processing, including a system for monitoring environmental conditions and for

cleaning and disinfecting the room and equipment to produce aseptic conditions, *see* 21 C.F.R. §§ 211.42(c)(10)(iv) and (v);

c. Establish and follow written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity that they purport or are represented to possess, *see* 21 C.F.R. § 211.100(a);

d. Review and approve all drug product production and control records to determine compliance with all established, approved written procedures before a batch is released or distributed, and thoroughly review and investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, *see* 21 C.F.R. § 211.192;

e. Employ an adequate quality control unit that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated, *see* 21 C.F.R. § 211.22(a);

f. Ensure that for each batch of drug product, there is an appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release, *see* 21 C.F.R. § 211.165(a);

g. Ensure appropriate laboratory testing for each batch of drug product purporting to be sterile and/or pyrogen-free that the drug product conformed to such requirements, *see* 21 C.F.R. § 211.167(a);

h. Establish a written testing program to assess the stability characteristics of drug products, *see* 21 C.F.R. § 211.166(a);

i. Ensure that personnel engaged in the manufacture, processing, packing, or holding of drug products wear clean clothing appropriate for the duties they perform, *see* 21 C.F.R. § 211.28(a);

j. Ensure that equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature are provided when appropriate for the manufacture, processing, packing, or holding of a drug product, *see* 21 C.F.R. § 211.46(b); and

k. Train each person engaged in the manufacture, processing, packing, or holding of drug products to enable such persons to perform their assigned functions and ensure that each person responsible for supervising the manufacture, processing, packing, or holding of a drug product has the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess, *see* 21 C.F.R. § 211.25(a) and (b).

31. These observations establish that Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

32. Defendants violate 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, and holding do not comply with CGMP to assure that they meet the requirements of the Act as to

their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

33. Defendants also violate 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due to Subpotent Drugs

34. During the 2018 Inspection, FDA investigators observed that two lots of Defendants' drug, Lipo-MIC 12 (methylcobalamin, a form of vitamin B12), were subpotent for the ingredient choline chloride. Specifically, documentation from Defendants' third-party laboratory represents that this drug has an acceptance criteria of 90-110% for choline chloride. However, three repeat tests conducted by this laboratory on one lot of Defendants' Lipo-MIC 12 product found that the potency of choline chloride was 78.5%, 79.7%, and 80%, respectively. A test conducted by another third-party laboratory on a different lot of Defendants' Lipo-MIC 12 product found that the potency of choline chloride was 89%.

35. These observations establish that Defendants' Lipo-MIC 12 is adulterated within the meaning of 21 U.S.C. § 351(c).

36. Defendants violate 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(c) because Defendants' drug has a strength that differs from that which it purports or is represented to possess.

Unapproved New Drug

37. One of Defendants' compounded drugs, Testosterone Cypionate/Propionate 200 mg/10 mg/1 mL Injectable, is a new drug within the meaning of 21 U.S.C. § 321(p) in that it is not generally recognized as safe and effective because there are no published adequate and well-controlled clinical studies of this drug upon which qualified experts could conclude that the drug is safe and effective.

38. Drugs manufactured at an outsourcing facility in compliance with 21 U.S.C. § 353b are exempt from the new drug approval requirements under 21 U.S.C. § 355. 21 U.S.C. § 353b(a). To be entitled to that exemption, Defendants need to meet all of the statutory elements of 21 U.S.C. § 353b for each drug product. *See* 21 U.S.C. § 353b(a). At the time of the 2018 Inspection, the label for Defendants' Testosterone Cypionate/Propionate 200 mg/10 mg/1 mL Injectable failed to include the statement "This is a compounded drug" as required by 21 U.S.C. § 353b(a)(10)(A)(i). *See* 21 U.S.C. §§ 353b(a) and 353b(d)(4)(A). Thus, this drug product, which is a new drug, is not exempt from the Act's drug approval requirements. *See id*.

39. Defendants' drug, Testosterone Cypionate/Propionate 200 mg/10 mg/1 mL Injectable, lacks an approved NDA or ANDA, as required by 21 U.S.C. § 355, and is not otherwise exempt from approval under 21 U.S.C. § 355(i). Thus, this drug product is an unapproved new drug.

40. Defendants' distribution into interstate commerce of an unapproved new drug violates 21 U.S.C. § 331(d).

Misbranding Due to Inadequate Directions for Use

41. Due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, Defendants' drugs are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. As such, Defendants' drugs are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A).

42. "Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5. A prescription drug, by definition, cannot bear adequate directions for use by a layperson because such drug must be administered under the supervision of a licensed practitioner. *See* 21 U.S.C. § 353(b)(1). FDA has established exemptions for certain drug products from the requirements that labeling bear adequate directions for use, but because Defendants' drug products are unapproved new drugs, they do not satisfy the conditions for any of these exemptions. *See* 21 C.F.R. §§ 201.115, 201.100.

43. Because at time of the 2018 Inspection, Pharm D was registered as an outsourcing facility, it was required to comply with all of the requirements of 21 U.S.C. § 353b to be able to avail itself of the exemptions in that section. Because the labels for Defendants' Testosterone Cypionate/Propionate 200 mg/10 mg/1 mL Injectable failed to include the statement "This is a compounded drug" as required by 21 U.S.C. § 353b(a)(10)(A)(i), this compounded drug does not qualify for 21 U.S.C. § 353b's exemption from the requirement for adequate directions for use contained in 21 U.S.C. § 352(f)(1) and is thus misbranded. *See* 21 U.S.C. §§ 353b(a), 353b(d)(4)(A).

44. Defendants violate 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce,

an article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling of the drug fails to bear adequate directions for use, and the drug is not exempt from the requirements of 21 U.S.C. § 352(f)(1).

45. Defendants violate 21 U.S.C. § 331(k) by causing an article of drug that is not exempt from the requirements of 21 U.S.C. § 352(f)(1) to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce.

Prior Inspections, Recalls, and Warnings to Defendants

46. FDA previously inspected Pharm D between May and June 2015 ("2015 Inspection") and observed similar insanitary conditions and CGMP deficiencies, including, but not limited to, failure to conduct media fills that simulate routine production; failure to employ adequate systems for monitoring environmental conditions, for example, by failing to conduct active air sampling during aseptic operations; failure to use appropriate aseptic techniques while producing drug products intended to be sterile, for example, by conducting inadequate smoke studies and failing to adequately monitor pressure differentials; and failure to employ adequate systems to clean, maintain, and disinfect rooms and equipment used to produce aseptic drug products. An FDA investigator also observed during the 2015 Inspection that Defendants' drugs had labels that omitted information required by 21 U.S.C. § 353b(a)(10). Despite these violations, Defendants continued to manufacture drugs without taking adequate corrective actions.

47. At the close of the 2015 Inspection, the FDA investigator issued a FDA-483 to Defendant Luis De Leon and discussed the inspectional observations with him.

48. In October 2016, Pharm D conducted a voluntary recall of its testosterone cypionate 200 mg/mL in sesame oil product because it was incorrectly labeled as being prepared in "grapeseed oil," and its HCG cyanocobalamin 5000 U product because it was incorrectly labeled as containing 7500 U.

49. FDA issued a Warning Letter on December 8, 2016, to Defendant Luis De Leon notifying him that Pharm D's drug products were (a) adulterated because they were manufactured under insanitary conditions and in violation of CGMP, (b) unapproved new drugs, and (c) misbranded because their labeling failed to include adequate directions for use and was false. The Warning Letter further stated that Pharm D, as a registered outsourcing facility, failed to submit a report identifying the drug products compounded during the previous six-month period. The Warning Letter noted that the failure to take prompt action to correct deficiencies could result in legal action without further notice, including seizure or injunction.

50. Despite promises to correct their deficiencies, Defendants' violations persisted, as evidenced by the violations observed during the 2018 Inspection.

51. Plaintiff is informed and believes that, unless restrained by the Court, Defendants will further violate 21 U.S.C. §§ 331(a), (k), and (d), in the manner alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing any article of drug, unless and until Defendants bring their manufacturing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Permanently restrain and enjoin under 21 U.S.C. § 332(a) Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A), 351(a)(2)(B), and/or 351(c), and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Violating 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce; and

C. Violating 21 U.S.C. § 331(d) by introducing and/or causing the introduction into interstate commerce, and/or delivering and/or causing the delivery for introduction into interstate commerce, of any new drug that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections, including testing and sampling, to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such relief as the Court deems just and proper.

DATED this 20th day of May, 2019.

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CERTIFICATE OF SERVICE

I hereby certify that on March 20, 2019, a true copy of the foregoing document was filed with Clerk, U.S. District Court, Southern District of Texas by way of CM/ECF and was served upon all counsel by electronic mail:

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JS 44 (Rev. 06/17) - TXSD (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

See Attachment

DEFENDANTS

Pharm D Solutions, LLC; Luis R. De Leon; Juan C. De Leon

County of Residence of First Listed Defendant Harris
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

See Attachment

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
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- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
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- ☐ 371 Truth in Lending
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- ☐ 690 Other

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- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
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- ☐ 835 Patent - Abbreviated New Drug Application
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- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a), 331(k), 331(d)

Brief description of cause:
Introduction of adulterated drugs into interstate commerce; adulteration while held for sale; unapproved new drugs

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $ CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE _____ DOCKET NUMBER _____

DATE 05/20/2019

SIGNATURE OF ATTORNEY OF RECORD Raquel Toledo

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____